Package leaflet: information for the user

Loproc® 20 mg, gastro-resistant capsules, hard
Loproc® 40 mg, gastro-resistant capsules, hard

Omeprazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What **Loproc®** is and what it is used for
2. What you need to know before you take **Loproc®**
3. How to take **Loproc®**
4. Possible side effects
5. How to store **Loproc®**
6. Contents of the pack and other information

1. What Loproc® is and what it is used for

Loproc® contains the active substance omeprazole. It belongs to a group of medicines called "proton pump inhibitors". It works by reducing the amount of acid your stomach produces.

Loproc® is used to treat the following conditions:

In adults:
- Gastro-oesophageal reflux disease (GORD). This occurs when the acid escapes from the stomach to the oesophagus (the tube that connects the throat to your stomach) causing pain, inflammation and heartburn in the stomach
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer)
- Ulcers infected with bacteria called "Helicobacter Pylori". If you have this condition, your doctor will also prescribe antibiotics to treat the infection and allow the ulcer to heal

- Ulcers caused by medicines called NSAIDs (Non Steroidal Anti-inflammatory Drugs). **Loproc®** can also be used to stop ulcers from forming if you are taking NSAIDs
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome)

In children:

Children over 1 year of age and ≥ 10kg

- Gastro-oesophageal reflux disease (GORD). This occurs when the acid escapes from the stomach to the oesophagus (the tube that connects the throat to your stomach) causing pain, inflammation and heartburn in the stomach

In children, the symptoms of this condition may include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

Children and adolescents over 4 years of age

- Ulcers infected with bacteria called "Helicobacter Pylori". If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal

2. What you need to know before you take Loproc®

Do not use Loproc®

- If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6)
- If you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole)
- If you are taking medicines containing **nelfinavir** (used for HIV infection).

Do not take **Loproc®** if any of the above applies to you. If you are not sure, contact your doctor or pharmacist before using **Loproc®**.

Warnings and precautions

Talk to your doctor or pharmacist before taking **Loproc®**

Severe cutaneous reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized pustular rash have been reported in association with omeprazole treatment. Stop using omeprazole and seek medical attention immediately if you notice any symptom related to these severe cutaneous reactions described in item 4.

Loproc® may hide the symptoms of other diseases. Therefore, if any of the following happened to you before you started taking **Loproc®** or while taking it, contact your doctor immediately:

- You lose a lot of weight for no reason and have problems swallowing
- You have stomach pain or indigestion
- You start to vomit food or blood

- You pass black stools (blood-stained stools)
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea
- You have severe liver problems
- You have ever had a skin reaction after treatment with a medicine similar to **Loproc®** that reduces stomach acid
- You are due to have a specific blood test (Chromogranin A)

If you are taking **Loproc®** on a long-term basis (more than 1 year), your doctor will probably keep you under regular monitoring. You should report any new and exceptional symptoms and incidents whenever you visit your doctor.

Taking a proton pump inhibitor such as **Loproc®**, especially over a period of more than one year, may slightly increase the risk of hip, wrist and spine fracture. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which may increase the risk of osteoporosis).

If you get a skin rash, especially in areas of the skin exposed to the sun, tell your doctor as soon as possible, as you may need to stop treatment with **Loproc®**. Remember to also mention any other ill-effects like pain in your joints.

When taking omeprazole, there is a possibility of kidney inflammation. Signs and symptoms may include decreased urine volume or blood in the urine and/or hypersensitivity reactions, such as fever, rash, and joint stiffness. You should report these signs to the treating doctor.
This medicine can affect the way in which your body absorbs vitamin B_{12}, particularly if you have to take it for a long period of time. Contact your doctor if you notice any of the following symptoms, which might indicate low levels of vitamin B_{12}:

- Intense fatigue or lack of energy
- Feeling of numbness or tingling
- Pain or redness of the tongue, mouth ulcers
- Muscle weakness
- Vision disturbances
- Memory problems, confusion, depression

Children
Some children with chronic conditions may require long-term treatment although it is not recommended. Do not give this medicine to children under 1 year of age or < 10 kg.

Other medicines and Loproc®
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription. This is

because **Loproc®** may affect the way certain medicines work and certain medicines may have an effect on **Loproc®**.

Do not take **Loproc®** if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus)
- Digoxin (used to treat heart problems)
- Diazepam (used to treat anxiety, to relax the muscles or in epilepsy)
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor should monitor you when you start or stop taking **Loproc®**
- Medicines used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking **Loproc®**
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (Hypericum perforatum) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to protect against blood clots)
- Erlotinib (used to treat cancer)
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) - if you are taking a high dose of methotrexate, your doctor may temporarily stop your treatment with **Loproc®**

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as **Loproc®** to treat ulcers caused by infection with Helicobacter Pylori, it is very important that you tell your doctor about any other medicine you are taking.

Loproc® with food and drink
See section 3.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Omeprazole is excreted in human milk, but is not likely to affect the child when therapeutic doses are used. Your doctor will decide whether you can take **Loproc®** if you are breast-feeding.

Driving and using machines

Loproc® is not likely to affect the ability to drive or use certain tools or machinery. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Loproc® capsules contain sucrose
Loproc® capsules contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Loproc®

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are.
The recommended dose is:

Adults

To treat GORD symptoms such as **heartburn and acid regurgitation**:
- If your doctor has found that the food tube (oesophagus) has been slightly damaged, the recommended dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks, if your oesophagus has not yet healed
- The recommended dose once the oesophagus heals is 10 mg once a day
- If your oesophagus has not been damaged, the usual dose is 10 mg once a day

To treat **ulcers in the upper part of the intestine** (duodenal ulcer):
- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks, if your ulcer has not healed
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 4 weeks

To treat **stomach ulcer** (gastric ulcer):
- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks, if the ulcer has not healed
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 8 weeks

To **prevent the duodenal and stomach ulcers from coming back**:
- The recommended dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat **duodenal and stomach ulcers caused by NSAIDs** (Non Steroidal Anti-Inflammatory Drugs):

- The recommended dose is 20 mg once a day for 4-8 weeks

To **prevent duodenal and stomach ulcers if you are taking NSAIDs**:

- The recommended dose is 20 mg once a day

To treat **ulcers caused by Helicobacter Pylori infection** and to stop them coming back:

- The recommended dose is 20 mg **Loproc®** twice a day for one week
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole

To treat too much acid in the stomach caused by a **growth in the pancreas (Zollinger-Ellison syndrome)**:

- The recommended dose is 60 mg daily
- Your doctor will adjust the dose according to your needs and will also decide how long you will need to take the medicine for

Use in children and adolescents

To treat GORD symptoms such as **heartburn and acid regurgitation**:

- Children over 1 year of age and weighing more than 10 kg can take **Loproc®**. The dose for children is based on the child's weight and the doctor will decide the correct dose

To treat **ulcers caused by Helicobacter Pylori infection** and to stop them coming back:

- Children over 4 years of age can take **Loproc®**. The dose for children is based on the child's weight and the doctor will decide the correct dose
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child

Taking this medicine

- It is recommended that you take the capsules in the morning
- You can take the capsules with food or on an empty stomach
- Swallow the capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain enteric-coated granules that prevent the medicine from being broken down by the stomach acids. It is important not to damage the granules.

What to do if you or your child have trouble swallowing the capsules

If you or your child have trouble swallowing the capsules:

- Break the capsules and swallow the contents directly with half a glass of water or pour the contents into a glass of water (non-fizzy), any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce
- Always stir the mixture just before drinking it (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes
- To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine – do not chew or crush them

If you take more Loproc® than you should
If you take more **Loproc®** than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Loproc®
If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Loproc®
Do not stop taking **Loproc®** without first talking to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following rare but serious side effects, stop taking this medicine and contact a doctor immediately:

- Sudden wheezing, swelling of the lips, tongue and throat or body, rash, fainting or difficulty swallowing (severe allergic reaction) (rare) Redness of the skin with blisters or peeling. There may also be blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be "Stevens-Johnson syndrome" or "toxic epidermal necrolysis". (very rare)
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). (rare).
- Widespread red, scaly rash with bumps under the skin and blisters accompanied by fever. The symptoms usually occur at the start of treatment (acute generalized pustular rash). (rare). Yellow skin, dark urine and tiredness, which may be symptoms of liver problems(rare)

Other side effects include:
Common side effects (may affect up to 1 in 10 users)

- Headache
- Effects on your stomach or intestine: diarrhoea, stomach pain, constipation, wind (flatulence)
- Feeling sick (nausea) or being sick (vomiting)
- Benign polyps in the stomach

Uncommon side effects (may affect up to 1 in 100 users)

- Swelling of the feet and ankles
- Disturbed sleep (insomnia)
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy
- Spinning feeling (vertigo)
- Changes in blood tests that check how the liver is working
- Skin rash, lumpy rash (hives) and itchy skin
- General feeling of being unwell and lacking energy

Rare side effects (may affect up to 1 in 1,000 users)

- Blood problems, such as decreased number of white blood cells and platelets. This may cause weakness, bruising or make infections more likely
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps
- Feeling agitated, confused or depressed
- Taste changes
- Eyesight problems such as blurred vision
- Suddenly feeling wheezy or short of breath (bronchospasm)
- Dry mouth
- Inflammation of the inside of the mouth
- An infection called "thrush", which can affect the intestine and is caused by a fungus
- Hair loss (alopecia)
- Skin rash upon exposure to the sun
- Joint pains (arthralgia) or muscle pains (myalgia)
- Severe kidney problems (interstitial nephritis)
- Increased sweating

Very rare side effects (may affect up to 1 in 10,000 users)

- Changes in blood cell count including agranulocytosis (lack of white blood cells)
- Aggression
- Seeing, feeling or hearing things that are not there (hallucinations)
- Severe liver problems leading to liver failure and inflammation of the brain
- erythema multiforme
- Muscle weakness
- Enlarged breasts in men

Not known (frequency cannot be estimated from the available data)

- Inflammation of the intestine (leading to diarrhoea)
- If you take **Loproc®** for more than three months, it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor immediately. Low magnesium levels may also lead to a decrease in potassium or calcium levels in the blood. Your doctor may decide that you have regular blood tests to monitor magnesium levels
- Rash, possibly with pain in the joints

In very rare cases, **Loproc®** may affect white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. In this case, it is important that you give information about your medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the National Organization for Medicines, 284 Mesogeion Avenue, GR-15562 Cholargos, Athens, Greece, Tel: + 30 21 32040337, Fax: + 30 21 06549585. Website's: http://www.eof.gr & http://www.kitrinikarta.gr.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Loproc®

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month
- Do not store above 25^0C
- Store this medicine in the original package (blister) in order to protect from moisture
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Contents of the pack and other information

What Loproc® contains

- The active substance is Omeprazole. Each capsule (gastro-resistant capsule) contains 20 mg or 40 mg of Omeprazole

- The other ingredients are: Hydroxypropyl methylcellulose, Disodium monohydrogen orthophosphate dihydrate, Sodium lauryl sulfate, Low-substituted hydroxypropyl cellulose, Sucrose spheres, Titanium dioxide E171 CI77891, Light magnesium carbonate, Purified talc, Methacrylic acid-Ethyl acrylate copolymer, Polysorbate, Sodium hydroxide pellets, Polyethylene glycol
  Capsule shell: Blue dye E131 CI42051, Quinoline yellow E104 CI47005, Titanium dioxide E171 CI77891, Iron oxide yellow E172 CI77492, Gelatin

What Loproc® looks like and contents of the pack

- **Loproc®** 20 mg: gastro-resistant hard gelatin capsules with opaque white body and an opaque dark green cap, containing enteric-coated granules
- **Loproc®** 40 mg: gastro-resistant hard gelatin capsules with opaque white body and an opaque dark green cap, containing enteric-coated granules

Pack sizes:

For Loproc® 20mg & 40mg:

- Cardboard box containing 14 gastro-resistant hard capsules in two aluminium blisters (alu-alu blisters) of 7 capsules and package leaflet
- Cardboard box containing 28 gastro-resistant hard capsules in four aluminium blisters (alu-alu blisters) of 7 capsules and package leaflet

For Loproc® 40mg:

- Cardboard box containing 30 gastro-resistant hard capsules in five aluminium blisters (alu-alu blisters) of 6 capsules and package leaflet.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
NORMA HELLAS S.A.,
54 Menandrou Str., GR-10431 Athens,
tel: + 30 210 52 22 282, fax: +30 210 52 41 368,
email: info@normahellas.gr.

Manufacturer
Loproc® 20mg & 40mg gastro-resistant hard capsules
KLEVA S.A.
189 Parnithos Ave.,
GR-13671 Acharnai
Greece

Loproc® 40 mg: gastro-resistant hard capsules
RAFARM SA
Pusi-Hadji Agiou Louka,
GR-15451 Paiania, Attica
Greece

This leaflet was last revised on: 30/11/2023

Other sources of information
Detailed information on this medicine is available on the website of the National Organization for Medicines.

NORMA HELLAS S.A.

54 Menandrou Str., GR-10431 Athens.

Tel. +30 210 52.22.282 Fax +30 210 52.41.368

email: info@normahellas.gr, http: // www.normahellas.gr

